UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

B

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,377	01/15/2004	Audrey Goddard	P5002R1C1	5616

9157 7590 09/14/2006

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/758,377	GODDARD ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *93-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *93-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040301;20060315*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed January 15, 2004, is acknowledged and has been entered. Claims 1-77 have been canceled. Claims 78-92 have been added.

2. The preliminary amendment filed February 9, 2004, is acknowledged and has been entered.

3. The preliminary amendment filed August 12, 2004, is acknowledged and has been entered. Claims 78-92 have been canceled. Claims 93-102 have been added.

4. Claims 93-102 are pending in the application and are currently under prosecution.

Information Disclosure Statement

5. The information disclosures filed February 26, 2004, and March 13, 2006, have been considered. An initialed copy of each is enclosed.

Oath/Declaration

6. The declaration filed January 15, 2004, is defective, as Paul Polakis failed to date the declaration the day it was executed. A new declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Specification

7. The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be

respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Examples of improperly demarcated trademarks include Kodak™ (as used at page 90), Amersham™ (as used at page 91), and Qiagen™ (as used at page 94).

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 93-102 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The considerations that are made in determining whether a claimed invention is supported by either a specific and substantial asserted utility or a well-established utility are outlined by the published Utility Examination Guidelines (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: http://www.gpoaccess.gov/.

Briefly, a "specific and substantial" asserted utility is an asserted utility that is specific to the particular nature and substance of the claimed subject matter, and which would be immediately available for application in a "real-world" context by virtue of the existing information disclosed in the specification and/or on the basis of knowledge imparted by the prior art, such that its use would not require or constitute carrying out further research to identify or reasonably confirm its usefulness in this context. A "well-

established" utility is a credible, specific, and substantial utility, which is well known, immediately apparent, and implied by the specification, and based on the disclosure of the properties of a material or subject matter, either alone or taken with the knowledge of one skilled in the art.

Claims 93-102 are drawn to a method of binding an antibody to a human cell expressing a particular protein.

The claims recite no intended use or purpose, and moreover, the claimed invention elicits no specific effect, nor has any particular function.

As such, the claims are directed to an active step, rather than a useful process having any one particular objective or purpose.

Therefore, the claims amount to no more than a mere invitation to the artisan to elaborate or develop a useful process comprising the active step of binding an antibody to a human cell expressing a particular protein.

Inasmuch as the claimed invention has no requisite objective or purpose, it has no apparent utility, in and of itself; and the specificity and substantiality of its putative utility as an integral and active step of any one objective process, nor its credibility, can be assessed.

Furthermore, the claimed invention, in and of itself, has no well-established utility, which is specific, substantial and credible utility that might be immediately practiced to the benefit to the public.

The U.S. Supreme Court addressed the issue of utility under 35 U.S.C. § 101 in deciding *Brenner, Comr. Pats. v. Manson,* 148 U.S.P.Q. 689 (US SupCt, 1966). The Court expressed the opinion that all chemical compounds are "useful" to the chemical arts *when this term is given its broadest interpretation*; nonetheless, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The Court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point-where specific

> benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. Id., at 695.

Further, the Court opined,

> [W]e are [not] blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. Id., at 696.

It is submitted the instant situation is directly analogous to that which was addressed by the Court in deciding *Brenner, Comr. Pats. v. Manson*, since hereto it might be said that all antibody-antigen binding reactions are "useful" in the biochemical arts when the term is given its broadest interpretation, but nevertheless § 101 requires that an invention have either an immediately obvious or fully disclosed "real world" utility, which the claimed invention lacks because the specification does not disclose a currently available "real world" use for the claimed antibody-antigen binding reaction.

To employ the disclosure of the claimed method of binding an antibody to a human cell expressing a particular protein in any useful process would require further research, which should be regarded as constituting part of the inventive process. Because the specification does not disclose a currently available, "real world" use for the claimed invention, the requirements set forth under 35 U.S.C. § 101 have not been met.

To fulfill the requirements of § 101, the skilled artisan must be able to use a claimed invention in the manner asserted by Applicants' to provide some immediate benefit to the public. See *Nelson v. Bowler and Crossley*, 206 USPQ 881 (CCPA, 1980).

The existing information disclosed by Applicants' application would merely provide the artisan with an invitation to perform further investigations to discover how the claimed invention might be useful. Although such additional investigation might ultimately lead to a derivation of a specific benefit, an immediate benefit could not be derived from the use of the claimed invention because the existing information is insufficient to enable the artisan to use the claimed antibody-antigen binding reaction in a specific, substantial and credible manner to provide an immediate benefit. Although

the disclosure of the claimed polynucleotide might tomorrow command the grateful attention of the public, the Court has decided:

> [A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.

Brenner, Comr. Pats. v. Manson, 148 U.S.P.Q. 689 at 696 (US SupCt, 1966).

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 93-102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language.

The claims are too vague and indefinite to satisfy the requirement for clarity and particularity set forth under 35 U.S.C. § 112, second paragraph, for the following reasons:

The claims are directed to an omnibus subject matter, as they are directed to an active step, rather than a useful process having any one particular objective or purpose, which at first glance may conceivably be performed during any number of a vast plurality of objectively different processes.

What is the purpose or objective of practicing the invention? Is the invention regarded as a method for isolating a cell? Is it a method for labeling or marking a cell? Is it a method for detecting a cell? Is it a method for diagnosing a disease associated with the presence of the cell? Is it a method for modulating the activity of the protein expressed by the cell? Is it a method for inhibiting the growth of a cell expressing the protein? Is it a method for treating a disease associated with the presence of the cell?

To satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph, the claims *must* define the metes and bounds of the subject matter that is regarded as the invention by Applicant with the clarity and particularity necessary to permit the skilled artisan to know or determine infringing subject matter.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 93-102 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

What is the purpose or objective of practicing the invention? How is it to be used, and to what aim or objective?

Inasmuch as Inasmuch as the claimed invention has no requisite objective or purpose, it has no apparent utility, in and of itself, it has no apparent utility, in and of itself, the sufficiency of the disclosure to reasonably enable the skilled artisan to practice the invention, or any objective process comprising the invention as an integral and active step cannot be assessed.

Furthermore, because the claimed invention has no requisite objective or purpose, it has no apparent utility, in and of itself, the claims merely serve as an invitation to elaborate or develop a useful process comprising the active step of binding an antibody to a human cell expressing the protein to which the claims are directed. Any need to further elaborate or develop a utility for the claimed invention would constitute a need to perform undue and/or unreasonable experimentation.

MPEP § 2164.01 states:

> The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors, which have been outlined in the Federal Circuit decision of *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), include, but are not limited to, the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed. See also *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

14. Claims 93-102 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "new matter" rejection.

Claims 93-102 are not original claims; the claims were added by the amendment filed August 12, 2004. At page 4 of that amendment Applicant has asserted the claims introduce no new matter, as written support for the newly added claims is found in the specification, as originally filed, at page 71, line 33, through page 76, line 17.

Contrary to Applicant's assertion, however, it does not appear the specification, including the claims, as originally filed, provides adequate written support for the breadth of subject matter to which the instant claims are directed. Claims 93-102 are drawn to a method of binding an antibody to a human cell expressing a particular protein. The claims recite no intended use or purpose; and the claims require no effect. Accordingly, the claims are directed to a mere active step, but an active step that might be comprised within any number of a very large plurality of objectively different processes, few of which might be described in the instant specification at, for example,

page 71, line 33, through page 76, line 17, or elsewhere. Yet, no where in the specification does it appear the claimed invention (i.e., the active step of binding an antibody to a human cell expressing the protein) is described, in and of itself. In fact, the only recitation of the term "binding an antibody", in this instance, "to an antigen" appears in the specification at paragraph [0083] of the published application[1]; and that particular disclosure does not appear highly relevant to the claimed process, per se.

For these reasons, it appears the addition of new claims 93-102 has introduced new matter, thereby violating the written description requirement set forth under 35 U.S.C. § 112, first paragraph.

This issue might be remedied if Applicant were to point to other particular disclosures in the specification, including the claims, as originally filed, which are believed to provide the necessary written support for the language of the instant claims.

15. Claims 93-102 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001; hereafter "Guidelines"). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

Guidelines states:

> The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This

[1] U.S. Patent Application Publication No. 2004/0126807 A1.

> problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

Arguably, if the specification, as filed, were to provide sufficient written support for the claimed invention, it is aptly noted the Federal Circuit has explained that *in ipsis verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). *See also:* University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, even an original claim, which necessarily provides written description for itself, may still not constitute an adequate written description of the claimed subject matter, *which establishes that the inventor was in possession of the invention.*

In this instance, claims 93-102 are directed to a process comprising binding an antibody to a human cell expressing a particular protein; however, the claimed invention achieves no requisite effect, and has not objective or purpose. Rather, the claimed invention is merely *an active step* of which some other undisclosed or unclaimed process is comprised, and which has not been described with the requisite particularity by the instant claims to satisfy the written description requirement set forth under 35 U.S.C. § 112, first paragraph.

Applicant is reminded "generalized language may not suffice if it does not convey the detailed identity of an invention." *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Because the claimed invention has no objective or purpose, it is not possible to practice the claimed invention to achieve any one particular effect.

Accordingly, the claims would serve as a mere invitation to the artisan to develop a useful process comprising the active step of binding an antibody to a human cell expressing the protein.

While it might be plausible, given the disclosure, to develop useful processes that achieve different objectives or purposes, which comprise the active step of binding an antibody to a human cell that expresses the protein to which the claims are directed, Applicant is reminded that the written description provision of 35 U.S.C. § 112, first paragraph, is severable from its enablement provision. An adequate written description requires more than a mere statement that it is the invention.

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (CAFC 1991). See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016 (CAFC 1991); *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

"Regardless whether a compound is claimed *per se* or a method is claimed that entails the use of the compound, the inventor cannot lay claim to the subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods". *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1984 (CAFC 2004).

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
September 11, 2006